Epizyme Announces Preclinical and Clinical Data to be Presented in Oral and Poster Sessions at Upcoming Medical Conferences in June

May 12, 2021

- Oral Presentation of Preclinical Data on Inhibition of SETD2, a Histone Methyltransferase, in Multiple Myeloma to be Presented at the European Hematology Association (EHA) Congress
- Poster Presentation for Tazemetostat, a Methyltransferase Inhibitor, in Epithelioid Sarcoma at the American Society of Clinical Oncology (ASCO) Meeting

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 12, 2021-- Epizyme, Inc. (Nasdaq: EPZM), a fully integrated, commercial-stage biopharmaceutical company developing and delivering novel epigenetic therapies, today announced that new preclinical and clinical data will be presented at upcoming medical meetings in June.

“We look forward to sharing our preclinical data at EHA that provide the therapeutic rationale for targeting SETD2 in multiple myeloma and are so pleased that it has been chosen for an oral presentation. These data are the basis for moving our SETD2 inhibitor program forward and, as we have previously reported, we remain on track for our planned IND submission in mid-2021 and plan to initiate a first-in-human clinical trial by year end,” said Dr. Jeffery Kutok, Epizyme’s Chief Scientific Officer. “As our SETD2 inhibitor program began to take shape, we were struck by the many parallels we saw with our EZH2 inhibitor, TAZVERIK® (tazemetostat). SETD2 is a histone methyltransferase, like EHZ2, and plays multiple key roles in cellular processes and cancer. We're excited about the potential of SETD2 inhibition in several settings, including high-risk t(4;14) myeloma, and more broadly in myeloma without the t(4;14) mutation, as well as other B-cell malignancies. We see potential as a monotherapy, as well as in combination with existing and emerging therapies in myeloma, with preclinical data also showing synergy with tazemetostat.”

“We are excited to share safety and preliminary activity data related to the EZH-301 confirmatory study of tazemetostat in Epithelioid Sarcoma (ES) at ASCO, a key milestone toward our goal of demonstrating the benefits of tazemetostat to patients in earlier lines of treatment for ES and Follicular Lymphoma by exploring combinations with standard of care therapies,” said Dr. Shefali Agarwal, Executive Vice President and Chief Medical and Development Officer at Epizyme. “As we outlined during our recent Vision Call, we plan to further explore tazemetostat as both monotherapy and in combinations across multiple hematologic and solid tumor cancers in clinical studies, which are on track to initiate later this year.”

Details of the presentations are listed below:

EHA Oral Presentation

Title: Discovery of a selective inhibitor of the SETD2 histone methyltransferase with potent in vitro and in vivo activity in preclinical models of multiple myeloma
Session: Basic and translational myeloma research
Presenter: Dr. Jennifer Totman
Abstract Code: S176
Live Q&A: Monday, June 14; 2021 8:45-9:30 p.m. CEST/2:45-3:30 p.m. EDT.

The EHA abstracts are available at https://ehaweb.org. All oral and poster presentations will be available on the EHA website on Friday, June 11, 2021 at 9:00 a.m. CEST/3:00 a.m. EDT.

ASCO Poster Presentation

Title: Results of the phase 1b soft-tissue sarcoma (STS) portion of the global randomized, double-blind, placebo-controlled study of tazemetostat (TAZ) plus doxorubicin (DOX) as frontline therapy for advanced epithelioid sarcoma (ES)
Session: Sarcoma
Presenter: Sant P. Chawla, M.D.
Abstract No.: 11563

The ASCO abstracts are available at https://meetinglibrary.asco.org. All oral and poster presentations will be available on the ASCO website on Friday, June 4, 2021 at 9:00 a.m. EDT.

About TAZVERIK® (tazemetostat)
TAZVERIK is a methyltransferase inhibitor indicated for the treatment of:

- Adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.
- Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies.
- Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.

These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

The most common (≥20%) adverse reactions in patients with epithelioid sarcoma are pain, fatigue, nausea, decreased appetite, vomiting and constipation. The most common (≥20%) adverse reactions in patients with follicular lymphoma are fatigue, upper respiratory tract infection, musculoskeletal pain, nausea and abdominal pain.

View the U.S. Full Prescribing Information here: Epizyme.com

About Epizyme, Inc.
Epizyme, Inc. is a fully integrated, commercial-stage biopharmaceutical company committed to its mission of rewriting treatment for cancer and other serious diseases through novel epigenetic medicines. In addition to an active research and discovery pipeline, Epizyme has one U.S. FDA approved product, TAZVERIK® (tazemetostat), for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma (ES) who are not eligible for complete resection; adult patients with relapsed or refractory follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies; and adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options. These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials(s). The Company is also exploring the treatment potential of tazemetostat in investigational clinical trials in other solid tumors and hematological malignancies, as a monotherapy and combination therapy in both relapsed and front-line disease settings. By focusing on the genetic drivers of disease, Epizyme seeks to match medicines with the patients who need them. For more information, visit www.epizyme.com.

TAZVERIK® is a registered trademark of Epizyme, Inc.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Epizyme, Inc. and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether commercial sales of TAZVERIK for epithelioid sarcoma and follicular lymphoma in the approved indications will be successful; whether tazemetostat will receive marketing approval for epithelioid sarcoma or follicular lymphoma in other jurisdictions, full approval in the United States or approval in any other indication; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials, such as the ongoing confirmatory trials; whether results from clinical studies will warrant meetings with regulatory authorities, submissions for regulatory approval or review by governmental authorities under the accelerated approval process; whether the company will receive regulatory approvals, including accelerated approval, to conduct trials or to market products; the impact of the COVID-19 pandemic on the company's business, results of operations and financial condition; whether the company's cash resources will be sufficient to fund the company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial success of tazemetostat; and other factors discussed in the "Risk Factors" section of the company's most recent Form 10-K or Form 10-Q filed with the SEC and in the company's other filings from time to time with the SEC. In addition, the forward-looking statements included in this press release represent the company's views as of the date hereof and should not be relied upon as representing the company's views as of any date subsequent to the date hereof. The company anticipates that subsequent events and developments will cause the company's views to change. However, while the company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so.

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